Complete Summary

GUIDELINE TITLE

Lipids and the primary prevention of coronary heart disease. A national clinical guideline.

BIBLIOGRAPHIC SOURCE(S)

Lipids and the primary prevention of coronary heart disease. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 1999. 60 p. (SIGN publication; no. 40). [234 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Coronary heart disease
- Hyperlipidemia

GUIDELINE CATEGORY

Prevention
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Cardiology
Family Practice
Internal Medicine
Nursing

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To assist clinicians, primary care teams, Health Boards and National Health Service (NHS) Trusts to prepare local guidelines to encourage the rational use of lifestyle measures and lipid lowering drugs for the primary prevention of coronary heart disease in high risk adults

TARGET POPULATION

Patients at high risk for coronary heart disease

INTERVENTIONS AND PRACTICES CONSIDERED

Prevention

1. Reduction of risk through lifestyle modification including smoking cessation (counseling, nicotine replacement therapy); dietary advice (Scottish Diet Action Plan, diet leaflet, advice by dietitian); salt restriction; weight reduction; physical activity; and reduction of alcohol use (Note: vitamin E and beta-carotene supplementation is considered but not recommended)
2. Treatment of hypertension with lifestyle modification
3. Prophylactic use of low-dose aspirin

Treatment - Lipid Lowering Drugs

1. Statins, such as pravastatin, simvastatin, lovastatin, atorvastatin, and fluvastatin
2. Fibrates including bezafibrate, ciprofibrate, clofibrate, fenofibrate, gemfibrozil
3. Resins including cholestyramine and colestipol
4. Other lipid lowering drugs including the nicotinic acid group (nicotinic acid, acipimox), fish oils (omega-3 marine triglycerides), and soluble fibre (ispaghula husk).
5. Combination therapy

Risk Assessment

1. Calculation of absolute risk
2. Risk assessment using the Sheffield Table, New Zealand Guidelines, or the Joint British Societies Coronary Risk Prediction Chart
3. Computerised scoring methods for risk assessment
4. Clinical assessment with lipid measurement of those at high risk
5. Laboratory tests including total cholesterol/high density lipoprotein ratio, serum triglycerides, and low density lipoproteins and very low density lipoproteins

Prevention in Women

1. Lipid lowering therapy
2. Hormone replacement therapy (HRT) (considered but not recommended)

Prevention in the Elderly

1. Lipid lowering therapy
2. Treatment of hypertension

Prevention in Patients with Diabetes Mellitus

1. Lipid lowering therapy
2. Use of a lower risk threshold in risk assessment

Prevention in Patients with Heterozygous Familial Hypercholesterolaemia

1. Diagnosis of heterozygous familial hypercholesterolaemia using tendon xanthomas, family history, and serum cholesterol as diagnostic markers.
2. Dietary advice
3. Statin therapy
4. Referral to specialists

MAJOR OUTCOMES CONSIDERED

- Coronary heart disease risk (absolute and relative risk)
- Serum total cholesterol levels, low-density lipoprotein cholesterol levels, high-density lipoprotein cholesterol levels
- Blood pressure reduction
- Smoking prevalence
- Coronary heart disease morbidity and mortality
- Homocysteine and folate levels
- Incidence of secondary coronary heart disease events (fatal and nonfatal), including myocardial infarction
- Incidence of primary coronary heart disease/coronary events (fatal and nonfatal), including myocardial infarction

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The standard SIGN search methodology was followed for a series of searches covering Embase, Healthstar and Medline from 1987 to 1997, as well as the Cochrane Library. These searches focused on systematic reviews, meta-analyses, and randomised controlled trials. Terms relating to hyperlipidemia were linked with terms covering risk assessment, lifestyle factors, and drug therapy.

Supplementary searches on the use of diet or exercise to reduce lipid levels were carried out, going back to 1966. Full listings of the search strategies are available from the SIGN Secretariat.

The results of supplementary searches carried out by members of the development group were added to the evidence base. Economic issues were covered by independent searches carried out by the former Scottish Health Purchasing Information Centre (SHPIC).

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Statements of Evidence:

Ia: Evidence obtained from meta-analysis of randomized controlled trials.

Ib: Evidence obtained from at least one randomized controlled trial.

IIa: Evidence obtained from at least one well-designed controlled study without randomization.

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study.

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.

IV: Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Scottish Intercollegiate Guidelines Network (SIGN) carries out comprehensive systematic reviews of the literature using customized search strategies applied to a number of electronic databases and the Internet. This is often an iterative process whereby the guideline development group will carry out a search for existing guidelines and systematic reviews in the first instance and, after the

results of this search have been evaluated, the questions driving the search may be redefined and focused before proceeding to identify lower levels of evidence.

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. SIGN has developed checklists to aid guideline developers to critically evaluate the methodology of different types of study design. The result of this assessment will affect the level of evidence allocated to the paper, which in turn will influence the grade of recommendation it supports.

Additional details can be found in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]). Available from the SIGN Web site.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The process for synthesizing the evidence base to form graded guideline recommendations is illustrated in the companion document titled "SIGN 50: A Guideline Developer's Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50], available from the SIGN website.

Evidence tables should be compiled, summarizing all the validated studies identified from the systematic literature review relating to each key question. These evidence tables form an important part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

In order to address how the guideline developer was able to arrive at their recommendations given the evidence they had to base them on, SIGN has introduced the concept of considered judgement.

Under the heading of considered judgement, guideline development groups are expected to summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- Generalisability of study findings
- Applicability to the target population of the guideline
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources need to treat them.)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgement. Once they have considered these issues, the group are asked to summarise their view of the evidence and

assign a level of evidence to it, before going on to derive a graded recommendation.

The assignment of a level of evidence should involve all those on a particular guideline development group or subgroup involved with reviewing the evidence in relation to each specific question. The allocation of the associated grade of recommendation should involve participation of all members of the guideline development group. Where the guideline development group is unable to agree a unanimous recommendation, the difference of opinion should be formally recorded and the reason for dissent noted.

The recommendation grading system is intended to place greater weight on the quality of the evidence supporting each recommendation, and to emphasise that the body of evidence should be considered as a whole, and not rely on a single study to support each recommendation. It is also intended to allow more weight to be given to recommendations supported by good quality observational studies where randomised controlled trials (RCTs) are not available for practical or ethical reasons. Through the considered judgement process guideline developers are also able to downgrade a recommendation where they think the evidence is not generalisable, not directly applicable to the target population, or for other reasons is perceived as being weaker than a simple evaluation of the methodology would suggest.

On occasion, there is an important practical point that the guideline developer may wish to emphasise but for which there is not, nor is their likely to be, any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it. These are marked in the guideline as "good practice points." It must be emphasized that these are not an alternative to evidence-based recommendations, and should only be used where there is no alternative means of highlighting the issue.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendations

Grade A: Requires at least one randomized controlled trial (RCT) as part of a body of literature of overall good quality and consistency addressing the specific recommendation (Evidence levels Ia, Ib).

Grade B: Requires the availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation (Evidence levels IIa, IIb, III).

Grade C: Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (Evidence level IV).

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group.

COST ANALYSIS

Cost-effectiveness of Statins for Primary Prevention

The cost-effectiveness of statins in primary prevention of coronary heart disease (CHD) has not been clearly defined. Primary prevention is less cost-effective than secondary prevention because of the lower absolute risk of coronary heart disease, except in high risk patients. Three published analyses have come to different conclusions, because of differences in models and assumptions, hence consensus on this issue is difficult. Cost-effectiveness also depends on the baseline risk and current cost of statins, which may alter with further price competition and the future introduction of generic versions. More detailed analyses of the cost-effectiveness implications of statin therapy related to the risk of coronary heart disease and cost of drug treatment have been prepared. See the original guideline document for a detailed review.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

1. National open meeting discusses the draft recommendations of each guideline.
2. Independent expert referees review the guideline.
3. The Scottish Intercollegiate Guidelines Network (SIGN) Editorial Board reviews the guideline and summary of peer reviewers' comments.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC): In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the full-text guideline document.

The strength of recommendation grading (A-C) and level of evidence (Ia-IV) are defined at the end of the "Major Recommendations" field.

Key Recommendations

A - Lifestyle measures remain the first priority in the primary prevention of coronary heart disease.

A - Absolute rather than relative risk reduction gives a better estimate of the benefits of lipid lowering drug treatment.

B - The first priority for lipid lowering drug therapy are patients with pre-existing cardiovascular disease.

C - A patient should be considered for lipid lowering drug therapy for primary prevention, usually following a trial of lifestyle measures and other appropriate interventions for at least three months, when the serum total cholesterol is ≥5.0 mmol/L and the 10 year risk of a major coronary event is ≥30% (equivalent to a one year risk ≥3%) using the Joint British Societies Coronary Risk Prediction Chart.

C - Women should be considered for lipid lowering drug therapy for primary prevention at the same risk threshold as men.

C - As for non-diabetics, lipid lowering drug therapy should be considered for primary prevention in Type 2 diabetics without evidence of nephropathy when the 10 year risk of a major coronary event is ≥30% using the Joint British Chart.

C - Current assessment methods may underestimate risk in Type 1 diabetics and in Type 2 diabetics with nephropathy. Lipid lowering drug therapy should be considered at a lower risk threshold in these individuals.

C - Patients with heterozygous familial hypercholesterolaemia should be treated aggressively with dietary advice and lipid lowering therapy. Close monitoring and follow-up is essential.

C - Targeted assessment should be undertaken in the age range 35 to 69 years, or at a younger age in patients with a family history of familial hypercholesterolaemia.

C - Secondary causes of dyslipidaemia should be excluded before commencing lipid lowering drug therapy.

For primary prevention of coronary heart disease, statins are now drugs of first choice for lowering lipids:

A - pravastatin

B - simvastatin

Lipid Lowering in Context: Lifestyle and Other Measures

A - Lifestyle measures remain the first priority in the primary prevention of coronary heart disease.

Smoking

B - All patients should be actively discouraged from smoking.

B - Repeated brief and supportive advice on smoking cessation should be given to patients by members of the primary care team.

A - Nicotine replacement therapy should be considered routinely in smokers attempting to quit.

Dietary Advice

B - Diets naturally rich in antioxidants (fruit and vegetables) may be protective against coronary heart disease. A higher intake of fruit and vegetables is recommended.

A - Vitamin supplementation with vitamin E (alpha-tocopherol) or beta carotene is not recommended for the primary prevention of coronary heart disease.

A - Dietary sodium intake should be reduced towards recommended levels of 100 mmol or 6 g salt per day.

C - The Scottish Diet Action Plan is recommended for primary prevention at a population level.

A - Advice for a healthy diet will include increasing starchy carbohydrate, fruit and vegetables, while reducing saturated fat, sugar and salt. This advice can be given by diet leaflet in the first instance.

C - More intensive dietary advice will require a detailed assessment of food intake by qualified dietitians or by other health professionals who have undergone appropriate training.

Obesity and Overweight

B - Realistic targets of 5 to 10 kg weight loss should be set for overweight and obese individuals.

B - A successful strategy for weight loss will include advice not only on diet and exercise, but also on behavioural change, support systems, and maintenance of reduced weight.

Alcohol

B - Alcohol intake up to 21 units weekly for men and up to 14 units weekly for women is acceptable for general health and may be protective against coronary heart disease. Men drinking more than 21 units weekly and women drinking more than 14 units weekly should reduce their consumption.

Physical Activity

B - For those who are currently inactive or not regularly active, aim to accumulate 30 minutes of moderate intensity physical activity on most days.

B - For those who are already active, vigorous intensity aerobic exercise of 20 to 30 minutes three times per week is recommended.

Other Measures for Preventing Coronary Heart Disease

A - Treatment of hypertension is recommended to reduce the risk both of coronary heart disease and stroke.

Lipid Lowering Drug Therapy

For primary prevention of coronary heart disease, statins are drugs of first choice for lowering lipids:

A - pravastatin

B - simvastatin

C - Drug choice should be made on the balance of trial evidence, safety and cost-effectiveness considerations; also by the degree of cholesterol lowering required to reach target levels in patients with severe hypercholesterolaemia.

B - The starting point for prevention is coronary heart disease event risk, and not simply cholesterol level, which is a poorer predictor of risk.

A - Absolute rather than relative risk reduction gives a better estimate of the benefits of lipid lowering drug treatment.

C - Any recommendation to intervene at a given threshold of risk must first consider the proportion of the population identified for drug treatment.

B - The first priority for lipid lowering drug therapy are patients with pre-existing cardiovascular disease.

Guidelines for Selecting Patients for Statin Therapy

C – A patient should be considered for lipid lowering drug therapy for primary prevention, usually following a trial of lifestyle measures and other appropriate interventions for at least three months, when the serum total cholesterol is $\geq$ 5.0 mmol/L and the 10 year risk of a major coronary event is $\geq$ 30% (equivalent to a one year risk $\geq$ 3%) using the Joint British Societies Coronary Risk Prediction Chart.

Primary Prevention in Women

C - As in men, lipid lowering drug therapy should be considered for primary prevention in women when the 10 year risk of a major coronary event is $\geq$ 30% using the Joint British Chart.

Primary Prevention in People with Diabetes Mellitus

C - As for non-diabetics, lipid lowering drug therapy should be considered for primary prevention in Type 2 diabetics without evidence of nephropathy when the 10 year risk of a major coronary event is $\geq$ 30% using the Joint British Chart.

C - Current assessment methods may underestimate risk in Type 1 diabetics and in Type 2 diabetics with nephropathy. Lipid lowering drug therapy should be considered at a lower risk threshold in these individuals.

Primary Prevention in Heterozygous Familial Hypercholesterolaemia

C - Patients with heterozygous familial hypercholesterolaemia should be treated aggressively with dietary advice and lipid lowering therapy. Close monitoring and follow-up is essential.

C - Referral to a specialist clinic is recommended, not only for treatment but also for genetic counselling.

Practical Issues: Risk Assessment, Follow-up and Referral

C - Lipid measurement is recommended if clinical and risk assessment suggests that a high total cholesterol/ high density lipoprotein ratio might influence future management.

C - Targeted assessment should be undertaken in the age range 35 to 69 years, or at a younger age in patients with a family history of familial hypercholesterolaemia.

B - The total cholesterol/high density lipoprotein ratio is preferred to total cholesterol when calculating risk.

C - Secondary causes of dyslipidaemia should be excluded before commencing lipid lowering drug therapy.

Follow-up: Target Cholesterol Levels

B - The treatment target total cholesterol level for primary prevention in patients on drug therapy should be <5.0 mmol/L, together with a fall in total cholesterol of at least 1 mmol/L.

Definitions:

Grades of Recommendations:

A. Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation. (Evidence levels Ia, Ib)
B. Requires the availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation. (Evidence levels IIa, IIb, III)
C. Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality. (Evidence level IV)

Statements of Evidence

Ia
Evidence obtained from meta-analysis of randomized controlled trials.

Ib
Evidence obtained from at least one randomized controlled trial.

IIa
Evidence obtained from at least one well-designed controlled study without randomization.

IIb
Evidence obtained from at least one other type of well-designed quasi-experimental study.

III
Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.

IV
Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

CLINICAL ALGORITHM(S)

An algorithm is provided for the screening and management of hyperlipidaemia in individuals at high risk of coronary heart disease.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The specific type of supporting evidence is explicitly identified in each section of the guideline.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Multiple risk factor interventions in individuals:

A recent overview of trials of multiple risk factor interventions for preventing coronary heart disease pooled data from 14 randomised comparisons of multifactorial interventions comprising one million person years of observation. This review included the results of four United Kingdom primary care based primary prevention studies: Oxford and Collaborators Health Check (OXCHECK), Family Heart Study, Cost-effectiveness of Lipid Lowering Study, and the Abingdon Trial. The main outcome measures were a net decrease in blood pressure of 2.3/1.1 mm Hg, in trials in which antihypertensive drugs were not used; a reduction of smoking prevalence of 4.2%; and a net decrease in serum cholesterol of 0.14 mmol/l. These changes were associated with nonsignificant falls in

coronary heart disease mortality of 4% and in total mortality of 3%. The authors concluded that health promotion interventions in these studies resulted in only small changes in risk factors and mortality rates in the general population, although there were beneficial effects in individuals within high risk groups. Evidence continues to emerge of the importance of more sensitive matching of interventions to individuals and of the need to take readiness to change into account.

Population interventions:

In contrast to the limited benefit from multifactorial risk factor intervention, a mass population intervention strategy, initiated during the 1970s in North Karelia, Finland, has been associated with a significant fall in coronary heart disease mortality of about 50% in that region. The North Karelia project was not a randomised trial of multifactorial intervention but nevertheless supports the view that lifestyle measures may impact on coronary heart disease morbidity and mortality if individuals and local populations are willing and able to make the necessary changes. Population interventions, such as the North Karelia project, must also address the social, economic and environmental circumstances which influence health. A recent publication, Deprivation and Health in Scotland, has confirmed that the incidence and mortality rates from acute myocardial infarction in those aged under 65 are higher in deprived areas.

The role of lipid lowering drugs for high risk patients:

Early trials using anion exchange resins or fibrates of limited potency recorded small reductions in fatal and non fatal coronary heart disease events with an increase in non cardiovascular mortality (WHO Clofibrate Study, Lipid Research Clinics Coronary Primary Prevention Trial, and the Helsinki Heart Study). Two primary prevention studies – the West of Scotland Coronary Prevention Study (WOSCOPS) and the Air Force/Texas Coronary Atherosclerosis Prevention Study (AFCAPS/TexCAPS) – and three secondary prevention studies the Scandinavian Simvastatin Survival Study (4S), the Cholesterol and Recurrent Events (CARE) study, and the Long-term Intervention with Pravastatin and Ischaemic Disease (LIPID) study – using statins (HMG CoA reductase inhibitors) have since shown clinically and statistically significant falls in fatal and non-fatal coronary heart disease. Because there were no adverse outcomes with statins in these trials, three of the five (WOSCOPS, 4S, and LIPID) were also able to show significant reductions in all cause mortality.

That lipid lowering with statins has produced beneficial effects is no longer in doubt, but it is only one of the mechanisms that contribute to coronary heart disease.

Subgroups Most Likely to Benefit:

People with diabetes mellitus: The higher absolute risk for cardiovascular disease in patients with diabetes suggests greater benefit from lipid lowering therapy than in non-diabetic subjects for a given cholesterol/high density lipoprotein ratio.

POTENTIAL HARMS

Aspirin: Gastrointestinal bleeding

Statins: Hepatotoxicity is the most common serious adverse effect, occurring in 1% of patients. Rhabdomyolysis is the most serious adverse effect, occurring in <0.1% of patients.

Fibrates: Fibrates, like statins, are generally well tolerated although myopathy is a recognised side effect.

Resins: Resins may raise serum triglycerides and gastrointestinal side effects can be troublesome.

Combination therapy: The small risk of myopathy that exists with statins and fibrates appears to be increased when they are used together and in the presence of pre-existing renal impairment.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve.

These parameters of practice should be considered guidelines only. Adherence to them will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor in light of the clinical data presented by the patient and the diagnostic and treatment options available.

Significant departures from the national guideline as expressed in the local guideline should be fully documented and the reasons for the differences explained. Significant departures from the local guideline should be full documented in the patient's case notes at the time the relevant decision is taken.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Lipids and the primary prevention of coronary heart disease. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 1999. 60 p. (SIGN publication; no. 40). [234 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Sep

GUIDELINE DEVELOPER(S)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

Scottish Executive Health Department

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Guideline Development Group: Professor Lewis Ritchie (Chairman); Dr Alan Begg; Dr Iain Broom; Mrs Jenny Brown; Mrs Kay Carr; Mrs Patricia Dawson, Director; Professor Charles Forbes; Dr John Forbes; Dr Andrew Harrower; *Dr Christopher Isles; Dr Kevin Jennings; Dr Jan Jones; *Professor Gordon Lowe; Dr Lesley MacDonald; Dr Robert Mack; Mr Andrew Millard; Professor Larry Ramsay.

*The guideline was drafted primarily by the members indicated in full consultation with other members of the guideline development group.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Scottish Intercollegiate Guidelines Network (SIGN) guideline development groups are required to complete a declaration of interests, both personal and non-personal. A personal interest involves payment to the individual concerned, e.g., consultancies or other fee-paid work commissioned by or shareholdings in the pharmaceutical industry; a non-personal interest involves payment which benefits any group, unit or department for which the individual is responsible, e.g., endowed fellowships or other pharmaceutical industry support. SIGN guideline group members should be able to act as independently of external commercial influences as possible, therefore, individuals who declare considerable personal interests may be asked to withdraw from the group. Details of the declarations of interest of any guideline development group member(s) are available from the SIGN executive.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline was issued in 1999 and will be considered for review in 2002.

Any updates to the guideline that result from the availability of new evidence will be noted on the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

Note from SIGN and the National Guideline Clearinghouse (NGC): In response to the U.S. Food and Drug Administration (FDA) withdrawal of the lipid-lowering agent cerivastatin, SIGN posted a "Guideline Update" specifically addressing the issue and its relevance to this guideline. See the "Companion Document" field of this NGC summary.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Scottish Intercollegiate Guidelines Network (SIGN) Web site:

- HTML format
- Portable Document Format (PDF)

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Quick reference guide: Lipids and the primary prevention of coronary heart disease. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 1999 Sep. 4 p. Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.
- Notice: Statins update: withdrawal of cerivastatin. August 31, 2001. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001 Aug. Please see the SIGN Web site for more information.
- SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001 Feb. (SIGN publication; no. 50). Electronic copies available from the SIGN Web site.

- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research and Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from the SIGN Web site.
- A background paper on the legal implications of guidelines. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network.

PATIENT RESOURCES

The following, published as annexes to the original guideline, are available from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

1. Annex 3. Example patient information leaflet. Your risk of heart disease: cholesterol and blood fats. In: Lipids and the primary prevention of coronary heart disease. Edinburgh (UK): Scottish Intercollegiate Guidelines Network, 1999 Sep. p. 35. (SIGN publication; no. 40).
2. Annex 7. Example diet sheet. Healthier eating: healthier heart. In: Lipids and the primary prevention of coronary heart disease. Edinburgh (UK): Scottish Intercollegiate Guidelines Network, 1999 Sept. p. 39-41. (SIGN publication; no. 40).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on January 3, 2002. The information was verified by the guideline developer as of February 4, 2002.

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